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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,526	10/30/2003	Paz Einat	68300-A/JPW/DNS	7662

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/697,526	EINAT ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 6-8 and 11, as specification drawn to a method for treatment of an apoptosis-related disease in a subject comprising administering an antibody, classified in class 424, subclass 130.1.

II. Claims 1-2, 4-7 and 9-11, as specifically drawn to a method of treatment for an apoptosis-related disease in a subject comprising administering an nucleotides, classified in class 514, subclass 44.

(Upon election of Group II, the applicant must choose **ONE** nucleotide SEQ ID NO from those listed in Claims 4 and 5, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

III. Claims 12 and 14, as specifically drawn to an antisense oligonucleotide having the sequence set forth in SEQ ID NO: 3, classified in class 536, subclass 23.1.

IV. Claims 13-14, as specifically drawn to an antisense oligonucleotide having the sequence set forth in SEQ ID NO: 4, classified in class 536, subclass 23.1.

V. Claim 15, as specifically drawn to a process for determining the susceptibility of a subject to a chemotherapeutic treatment of an apoptosis-related disease comprising; determining the level of ATRX polypeptide in a healthy individual compared to a subject, classified in class 435, subclass 7.1.

VI. Claim 16, as specifically drawn to a process for determining the susceptibility of a subject to a chemotherapeutic treatment of an apoptosis-related disease comprising:

determining the level of mRNA encoding the ATRX polypeptide in a healthy individual compared to a subject, classified in class 435, subclass 6.

VII. Claim 17, as specifically drawn to a process for determining the efficacy of a chemotherapeutic treatment administered to a subject comprising: determining the level of the ATRX polypeptide prior to and after treatment, wherein a high level prior to treatment compared to after indicates the efficacy of the treatment, classified in class 435, subclass 7.23.

VIII. Claim 18, as specifically drawn to a process for determining the efficacy of a chemotherapeutic treatment administered to a subject comprising: determining the level of the ATRX mRNA in the subject prior to and after treatment, wherein a high level prior to treatment compared to after indicates the efficacy of the treatment, classified in class 435, subclass 6.

IX. Claim 19, as specifically drawn to a process for diagnosing a cancer in a subject comprising: determining the level of ATRX polypeptide, classified in class 435, subclass 7.23.

X. Claim 20, as specifically drawn to a process for diagnosing a cancer in a subject comprising: determining the level of polynucleotide encoding the ATRX polypeptide, classified in class 435, subclass 6.

XI. Claims 21-22 and 24-25, as specifically drawn to a process for obtaining a compound which modulates apoptosis in a cell, classified in class 435, subclass 4.

XII. Claim 23, as specifically drawn to a process for obtaining a compound which promotes apoptosis in a cell, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

While the inventions of both Group III and Group IV are polynucleotides, in this instance the polynucleotide of Group III is 294 nucleotides in length, whereas the polynucleotide of Group IV is 296 nucleotides in length. The specification does not disclose that the two polynucleotides contain any structural similarity (see for example, Figure 3, pages 12/19 and 17/19). Thus the polynucleotides of Groups III and IV are structurally distinct molecules; any relationship between polynucleotides of Groups III and IV is dependent upon the correlation between the scope of the "sense" polynucleotide for which they are complementary to. Therefore, the polynucleotides are patentably distinct.

Furthermore, searching the inventions of Group III and Group IV would impose a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid sequence or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search for two different polynucleotides, and different polynucleotide segments in the databases, in addition to searching the organic molecule databases would require extensive searching and review.

The inventions of Groups I-II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method for treating an apoptosis related disease comprising administering an antibody (Group I), the method for treating an apoptosis related disease comprising administering an oligonucleotide (Group II) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups I-II are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-II have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-II.

The inventions of Groups V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The process for determining the susceptibility of a subject to a chemotherapeutic treatment by detecting the change in ATRX polypeptide (Group V), the process for determining the susceptibility of a subject to a chemotherapeutic treatment by detecting the change in mRNA encoding the ATRX polypeptide (Group VI), the process for determining the efficacy of a chemotherapeutic treatment by determining the change in ATRX polypeptide (Group VII), the process for determining the efficacy of a chemotherapeutic treatment by determining the change in mRNA encoding the ATRX polypeptide (Group VIII), the process for diagnosing a cancer in a subject by determining the level of ATRX polypeptide (Group IX) and the process for diagnosing a cancer in a subject by determining the level of mRNA that encodes a ATRX polypeptide (Group X) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for determining differ significantly for each of the materials. For determining the susceptibility, "healthy" individuals are used as a comparison to a subject, wherein a low level is indicative of susceptibility. For determining the efficacy, a patient that has already been determined to have a disease is used and the comparison is prior to treatment and after treatment. For diagnosing cancer, healthy individuals are used as a comparison to a subject, wherein a high level is indicative of cancer. Therefore, each method is divergent in materials, steps and outcome. For these reasons the inventions of Groups V-X are patentably distinct.

The inventions of Groups XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The process for obtaining a compound which modulates apoptosis in a cell (Group XI) and the process for obtaining a compound which promotes apoptosis in a cell (Group XII) are unrelated as they

comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for obtaining a compound differ significantly for each of the materials. For obtaining a compound which modulates apoptosis, a cell expressing ATRX polypeptide is contacted with a compound, wherein the compound may be an agonist or an antagonist. For obtaining a compound which promotes apoptosis, a control cell is treated with an apoptosis-stimulating agent which causes apoptosis in the control and not in the test. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups XI and XII are patentably distinct.

The inventions of Groups III-IV and the invention of Group II are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of treating an apoptosis related disease can be practiced with using a nucleotide sequence of SEQ ID NO: 3, a nucleotide sequence of SEQ ID NO: 4 or an antibody.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER